

AMENDMENTS TO THE CLAIMS:

Please cancel claims 3 and 16; amend claims 1, 4, 6, 8-13, 17, 21, 22 and 25; and add new claims 26-31 as set forth below:

1. (Amended) A medical device, comprising:

a substrate that is expandable from a compressed state to an expanded state;

a coating on said substrate, said coating having a drug agent incorporated therein,
wherein said drug agent comprises an anti-proliferative agent and is incorporated in said coating prior to delivering said medical device to a target location within a mammalian body; and

[a] an elastic sheath over said coating, said elastic sheath being expandable from a compressed state to an expanded state and having at least one perforation therein;

wherein when said substrate is in a compressed state, said elastic sheath is in a compressed state and said at least one perforation is substantially closed such that said drug agent does not pass through said at least one perforation; and

wherein when said substrate is in an expanded state, said elastic sheath is in an expanded state and said at least one perforation is substantially open such that said drug agent passes through said at least one perforation.

2. (Previously presented) The device of claim 1, wherein said coating comprises a polymer selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters, polyacrylamides, polyethers, polyurethane dispersions, acrylic latex dispersions, and mixtures and copolymers thereof.

3. (Canceled)

4. (Amended) The device of claim 1, wherein said elastic sheath comprises a material selected from the group consisting of ethylene vinyl acetate, latexes, urethanes, polysiloxanes, styrene-

ethylene/butylene-styrene block copolymers, aliphatic polyesters, and mixtures and copolymers thereof; and nitinol and stainless steel.

5. (Previously presented) The device of claim 1, wherein said at least one perforation is in the shape of a longitudinal slit.

6. (Amended) The device of claim 5, wherein said elastic sheath comprises a plurality of perforations arranged in a staggered pattern.

7. (Previously presented) The device of claim 1, wherein said substrate comprises at least part of a balloon portion of a balloon catheter.

8. (Amended) The device of claim 7, wherein said elastic sheath is tubular and surrounds said balloon portion of said balloon catheter, said tubular elastic sheath having proximal and distal ends.

9. (Amended) The device of claim 8, wherein said proximal and distal ends of said elastic sheath are attached to said balloon catheter such that said balloon portion is completely covered by said elastic sheath.

10. (Amended) The device of claim 9, wherein said proximal and distal ends of said elastic sheath are attached to said balloon catheter by an adhesive.

11. (Amended) The device of claim 9, further comprising a filament around said proximal and distal ends of said elastic sheath.

12. (Amended) A method for the localized delivery of a drug agent to a target location within a mammalian body, comprising the steps of:

providing a medical device comprising:

a substrate that is expandable from a compressed state to an expanded state;

a coating on said substrate; and

[a] an elastic sheath over said coating, said elastic sheath being expandable from a compressed state to an expanded state and having at least one perforation therein;

wherein when said substrate is in a compressed state, said sheath is in a compressed state and said at least one perforation is substantially closed; and

wherein when said substrate is in an expanded state, said sheath is in an expanded state and said at least one perforation in said expandable sheath is substantially open;

incorporating said drug agent into said coating, wherein said drug agent comprises an anti-proliferative agent;

delivering said medical device to said target location while said elastic sheath is in a compressed state and said at least one perforation is substantially closed; and

expanding said substrate to thereby expand said elastic sheath to an expanded state such that said at least one perforation is substantially open, whereby the drug agent passes through said at least one perforation.

13. (Amended) The method of claim 12, wherein said step of incorporating the drug agent into said coating comprises the steps of:

expanding said substrate to thereby expand said elastic sheath such that said at least one perforation is substantially open;

exposing said drug agent to said coating through said at least one perforation while said at least one perforation is substantially open; and

compressing said substrate to thereby compress said elastic sheath such that said at least one perforation is substantially closed.

14. (Previously presented) The method of claim 13, wherein said drug agent is exposed to said coating by immersing at least part of said medical device into a solution comprising said drug agent.

15. (Previously presented) The method of claim 12, wherein said coating comprises a polymer selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin,

polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters, polyacrylamides, polyethers, polyurethane dispersions, acrylic latex dispersions, and mixtures and copolymers thereof.

16. (Canceled)

17. (Amended) The method of claim 12, wherein said elastic sheath comprises a material selected from the group consisting of ethylene vinyl acetate, latexes, urethanes, polysiloxanes, styrene-ethylene/butylene-styrene block copolymers, aliphatic polyesters, and mixtures and copolymers thereof; and nitinol and stainless steel.

18. (Previously presented) The method of claim 12, wherein said at least one perforation is in the shape of a longitudinal slit.

19. (Previously presented) The method of claim 18, wherein said at least one perforation comprises a plurality of perforations arranged in a staggered pattern.

20. (Previously presented) The method of claim 12, wherein said substrate comprises at least part of a balloon portion of a balloon catheter.

21. (Amended) The method of claim 20, wherein said elastic sheath is tubular and surrounds said balloon portion of said balloon catheter, said tubular elastic sheath having proximal and distal ends.

22. (Amended) The method of claim 21, wherein said proximal and distal ends of said elastic sheath are attached to said balloon catheter such that said balloon portion is completely covered by said elastic sheath.

23. (Previously presented) The method of claim 12, wherein said medical device comprises an electroporation catheter.

24. (Previously presented) The method of claim 12, wherein said medical device comprises an iontophoresis catheter.

25. (Amended) A medical device, comprising:

a catheter comprising a balloon portion that is expandable from a compressed state to an expanded state;

a polymer coating on said balloon portion, said coating having a drug agent incorporated therein, wherein said drug agent comprises an anti-proliferative agent and is incorporated in said coating prior to delivering said medical device to a target location within a mammalian body;
and

a tubular elastic sheath over said coating, said elastic sheath being expandable from a compressed state to an expanded state and having a plurality of perforations therein, said perforations being arranged in a staggered pattern; wherein

the proximal and distal ends of said elastic sheath are attached to said catheter such that said balloon portion is completely covered by said elastic sheath;

when said balloon portion is in a compressed state, said elastic sheath is in a compressed state and said perforations are substantially closed such that said drug agent does not pass through said perforations; and

when said balloon portion is in an expanded state, said elastic sheath is in an expanded state and said perforations are substantially open such that said drug agent passes through said perforations.

26. (New) The medical device of claim 1, wherein said anti-proliferative agent comprises an agent selected the group consisting of paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors or a combination thereof.

27. (New) The medical device of claim 26, wherein said anti-proliferative agent comprises paclitaxel.
28. (New) The method of claim 12, wherein said drug agent comprises an anti-proliferative agent.
29. (New) The method of claim 28, wherein said anti-proliferative agent comprises an agent selected the group consisting of paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors or a combination thereof.
30. (New) The method of claim 28, wherein said anti-proliferative agent comprises paclitaxel.
31. (New) The medical device of claim 30, wherein said anti-proliferative agent comprises paclitaxel.